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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/309,199	05/10/1999	MARIO ASSENMACHER	212302000720	7207

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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/309,199

Applicant(s)

ASSENMACHER ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 22-32, 34-87 and 98-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-21, 33 and 88-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group II (Claims 14-21,33, 88-97) in Paper No. 21 filed on 04/18/02 is acknowledged.

The traversal is on the ground(s) that there would not be a serious burden of search and that the Office has previously search and examined the claimed subject matter. This is not found persuasive. Regarding applicant's comments about undue burden, the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criterion. The Inventions are distinct for reasons elaborated in paragraphs 3-7 of the previous Office Action (Paper No. 20).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13, 22-32, 34-50, 74-87, 98-115 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 14-21, 33, 88-97 are under consideration in the instant application.

2. The filing date of the instant claims is deemed to be the filing date of the instant application, i.e. 05/10/1999, as the previous provisional application 60/085136 does not support the claimed limitations of the instant application, encompassing methods of label antigen-specific T cells, wherein the secreted product specifically bound to the capture moiety. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

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3. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

4. After further consideration of Applicants response (Paper No 13) and Supplemental Information Disclosure Statement, particularly Brosterhus et al., the previous rejection under 112, first paragraph has been withdrawn.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14-17, 33, 88-92, 94, 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz et al. (Proc. Natl. Acad. Sci., 1995, 92, 1921-1925. see entire document)

Manz et al. teach a method to analysis and sorting of live cell according to secreted molecules (see entire document). The method comprises exposing the cell to an specific antigen, modifying the surface of a cell to contain a capture moiety specific for the product and culturing the cell under condition wherein the product is secreted, release and specifically bound to the capture moiety.

Manz et al. further teach that the label moiety and capture moiety is an antibody an antibody and that capture moiety can be couple to the cell surface of a cell through a lipid anchor (see Material and Methods and entire document).

Manz et al. also teach method of determining the amount and type of secreted product per cell (see Material and Methods).

Manz et al. do not explicitly teach that live cells are antigen-specific stimulated T-cells.

However, Manz et al. teach the artificial affinity matrix technology described in principle and established it for two different system of general interest - the characterization and sorting of hybridoma cells and cytokine-secreting T cells (see page 1925, last paragraph). Moreover, Manz et al. also teach murine splenic lymphocytes, (claim 97 recites that antigen-specific T-cells exist within a population of cells) that, in response to stimulation with staphylococcal enterotoxin (superantigen) , secreted cytokines (page 1924).

It is noted that, in the current specification as filed, Applicant stated that "for *in vivo* or *in vitro* exposure an antigen of the invention can be peptides, proteins, glycoproteins, lipids, cell extracts, tissue extracts, whole microorganisms, such as protozoans, bacteria and viruses" (page 28, lines 15-19). Moreover, Applicant further teaches that cytokines are known in the art to be secreted in response to specific antigen stimulation (page 30, line 15). Thus, the ordinary artisan at the time of invention would regard cytokine secreting T cells in response to stimulation with staphylococcal enterotoxin (superantigen) as been antigen-specific stimulated T cells.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of technology for analysis and sorting of live cells according to secreted molecules.

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7. Claims 14-17, 33, 88-92, 94, 97 are rejected under 35 U.S.C. 102(a) as being anticipated by Assenmacher et al. (Eur. J. Immunol.1998, 28, 1534-1543 see entire document).

Assenmacher et al. teach a cellular affinity matrix technology that allows labeling and isolation of cells according to any secreted product, against which a pair of antibodies, not inhibiting each other in binding to the antigen, is available (see Discussion, page 1538, paragraphs 3 and 4).

Assenmacher et al. also teach the method comprises exposing T-cells to an specific antigen, modifying the surface of a cell to contain a capture moiety specific for the product and culturing the cell under conditions wherein the product is secreted, release and specifically bound to the capture moiety (see Abstract and Materials and Methods).

Assenmacher et al. further teach that the label moiety and capture moiety is an antibody and that capture moiety can be coupled to the cell surface of T cell through a lipid anchor. (see Material and Methods and Discussion, page 1538, paragraph 5).

Assenmacher et al.. also teach method of determining the amount and type of secreted product, cytokines, per cell (see paragraph 4.6 of Material and Methods). Moreover, Assenmacher et al. teach that viability and cytokine production of activated T-cells in response to specific antigen stimulation are not influenced by biotinylation and affinity matrix labeling (see Discussion, page1538, paragraph 3).

Assenmacher et al. also teach that by immunofluorescent and immunohistochemical analysis of intracellular cytokine expression a valuable information about frequency and kinetics of specific cytokines and correlation of expression of various cytokines with specific antigens stimulation of T cells can be obtained (see Discussion, page 1538, paragraph 2.).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of referenced method to analyze to what extent individual superantigen-activated T cells contribute to the control of their own cytokine expression by sequential expression of IL-2, IFN- γ and IL-10.

8. Claims 14-17, 33, 88-97 rejected under 35 U.S.C. 102(b) as being anticipated by Miltenly et al. (WO 94/09117 see entire document).

Miltenly et al. teach a method to analysis and sorting of live cell according to secreted molecules. The method comprises exposing the cell to and specific antigen, modifying the surface of a cell to contain a capture moiety specific for the product and culturing the cell under condition wherein the product is secreted, release and specifically bound to the capture moiety. (see entire document, particularly pages 4-5).

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Miltenly et al. further teach that the label moiety and capture moiety is an antibody an antibody and that capture moiety can be couple to the cell surface of a cell through a lipid anchor and that antibody is bispecific (and entire document, particularly page 10, paragraph 1, page 11, paragraph 3, page 12, paragraph 1).

Miltenly et al. also teach method of determining the amount and type of secreted product per cell (see entire document, particularly page 16, paragraph 2).

Miltenly et al. teach that T cells specific cell surface molecules CD3 can be used to practice invention (page 10, line 28) and that various cell, including, but not limiting T cells which secrete a biological modifier are suitable as well (page 16, line 32).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the Miltenly et al.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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June 10, 2002

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